

Clinical Edit Criteria Proposal

Drug/Drug Class: Oxycontin[®]/Narcotic Analgesic

Prepared for: Missouri Medicaid

Prepared by: Heritage Information Systems, Inc.

☒ New Criteria

☐ Revision of Existing Criteria

Executive Summary

Purpose: To promote prudent prescribing and to reduce the costs associated with Oxycontin[®] (oxycodone hydrochloride).

Why was this Issue Selected: For the previous reporting period (August 2001 – July 2002), Missouri Medicaid paid \$12.3 million for Oxycontin SR products. This represents 1.5% of the total drug budget.

Program-specific information:	Drug	Claims	Expense
•	Oxycontin [®] (oxycodone hydrochloride SR)	55,292	\$12,300,761

Setting & Population:

Type of Criteria:

<input type="checkbox"/> Increased risk of ADE	<input type="checkbox"/> Non-Preferred Agent
<input checked="" type="checkbox"/> Appropriate Indications	<input type="checkbox"/> Other:

Data Sources:

<input type="checkbox"/> Only administrative databases	<input type="checkbox"/> Databases + Prescriber-supplied
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Purpose of PA Criteria

Under the Omnibus Budget Reconciliation Act of 1993, Congress intended Prior Authorization or Prior Approval (PA) programs to control utilization of products that have very narrow indications or high abuse potential. While prescription expenditures are increasing at double-digit rates, payors are also evaluating ways to control these costs by influencing prescriber behavior and guide appropriate medication usage. Prior authorization criteria assist in the achievement of qualitative and economic goals related to health care resource utilization. Restricting the use of certain medications can reduce costs by requiring documentation of appropriate indications for use, and where appropriate, encourage the use of less expensive agents within a drug class. Prior authorization criteria can also reduce the risk for adverse events associated with medications by identifying patients at increased risk due to diseases or medical conditions, or those in need of dosing modifications.

Why Has This Clinical Issue Been Selected For Review?

Oxycontin[®] (oxycodone hydrochloride), an opioid analgesic, received approval from the Food & Drug Administration (FDA) for the management of moderate to severe pain in patients who require treatment with an opioid analgesic for more than a few days.^{1,2,3,4} Oxycontin is formulated as a controlled-release tablet and allows administration every 12 hours.^{1,2,3,4}

Oxycontin[®] is available in different strengths (10, 20, 40, 80, and 160 mg).^{1,2,3,4} When initiating the dosage regimen, it is essential that this be done on an individual basis, evaluating the patient's prior analgesic treatments (opioid or non-opioid). Some things to pay attention to include: the patient's condition and medical status, the patient's opioid exposure and tolerance (if any), and the balance between adequate pain control and adverse effects.¹ Patients who are not already opioid tolerant, especially those who are receiving concurrent treatment with muscle relaxants, sedatives, or other CNS medications should start with the lowest initial dose of Oxycontin[®].¹ A reasonable dose for these patients is 10 mg every 12 hours.¹ After the initial dose is started, the patient needs to be evaluated at frequent intervals and the dose should be titrated to adequate effect. Dosage titration, if needed to obtain a balance between pain relief and opioid-related side effects, should be done every 1-2 days because steady-state plasma concentrations are within 24-36 hours.¹ Therefore, immediate-release or rescue medicine should be available to the patient in the event of breakthrough pain or to prevent pain that occurs predictably under certain patient activities.¹ In addition, dosing intervals shorter than 12 hours have not been studied in clinical trials.¹ Therefore, it is important to note that the q12 hours should be increased; not the dosing frequency.¹ For example, except for the increase from 10 to 20 mg every 12 hours, the total daily Oxycontin[®] dose can be increased by 25-50% of the current dose at each increase.⁵ When discontinuing Oxycontin[®] therapy, the dose needs to be slowly tapered. The package insert recommends that the daily dose be reduced by approximately 50% for the first two days and then reduced by 25% every two days thereafter until the total dose reaches the dose is 10 or 20 mg q 12 hours.¹ At this dose, therapy may be discontinued. Since Oxycontin[®] is a highly addicting drug, patients may experience withdrawal from the dose tapering. If this happens, tapering should be stopped. Instead, the dose should be slightly increased until the signs and symptoms of opioid withdrawal disappear. Then, tapering should begin again but this time with longer periods of time between each dose reduction.¹

Many physicians are prescribing Oxycontin[®] for various uses, such as osteoarthritis-related pain. Roth et al. found in their study that around-the-clock controlled-release oxycodone therapy was effective and safe for patients with chronic, moderate to severe, osteoarthritis pain.⁶



Use of Oxycontin[®] in children under the age of 18 years of age is not recommended as data on safety and effectiveness have not been established for this patient population.¹ However, according to the package insert, no specific increased risk is expected from the use of this form of oxycodone in children old enough to take tablets if dosing is adjusted for the patient's weight.¹ It is important to note that Oxycontin[®] tablets cannot be crushed or divided for administration because the drug may be released and absorbed all at once and, therefore, the patient may experience an overdose and could die.^{1,2,3,4,5}

In conclusion, Oxycontin[®] may be used to treat many types of moderate to severe pain. Therefore, it is essential that healthcare professionals evaluate the need for Oxycontin[®] on an individual basis and to determine if Oxycontin[®] is the most appropriate and cost-effective therapy.

Setting & Population

- Drug class for review: Oxycontin[®] (oxycodone hydrochloride)
- Age range: All ages
 - Claims for patients 18 years of age and under subject to clinical review
- Gender: males and females

Approval Criteria

Approval Diagnoses				
Condition	Submitted ICD-9 Diagnoses	Inferred Drugs	Date Range	Client Approval (Initials)
Cancer	140 - 239	NA	2 years	
	NA	Antineoplastics	12 months	
Opioid Tolerance*	NA	Opioids	> 7 days supply in the last 30 days	
Chronic nonmalignant pain (CNMP):	282-355 710-733.7	NA	1 year	
	NA	Non-opioid analgesics	90 days	

*Inferred diagnosis of opioid tolerance required only for 80mg and 160mg tablets

Approval Procedures				
Condition	Submitted ICD-9 Diagnoses*	Inferred Drugs	Date Range	Client Approval (Initials)
N/A				



Denial Criteria

- Current dose optimization edits
- 80 and 160mg strengths denied if patient does not have > 7 days of opioid therapy in the most recent 30 days of claims history.

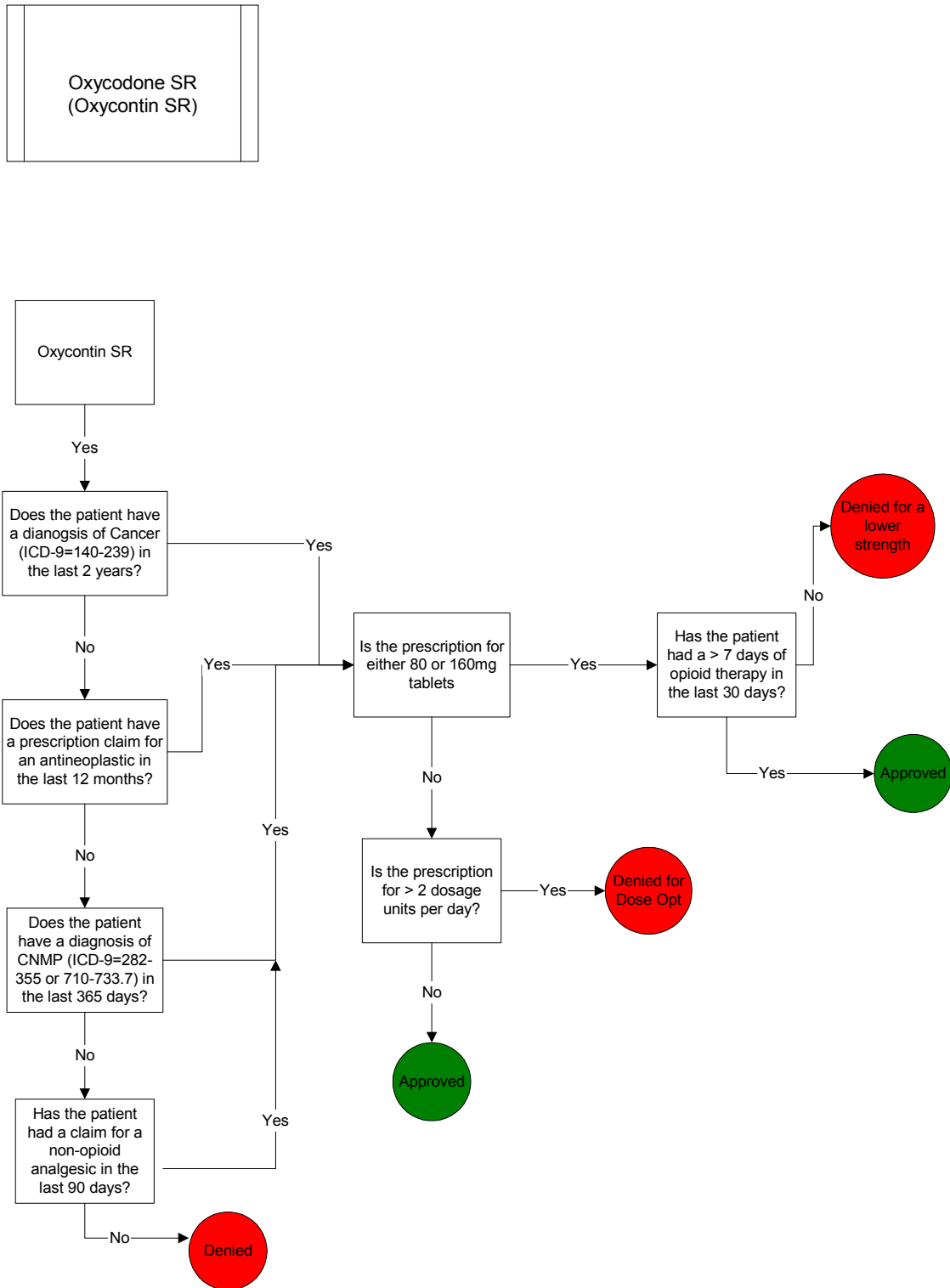
Required Documentation

Laboratory results:
MedWatch form:

Progress notes:
Other:



Flowchart of Criteria



References

1. Oxycontin® Package Insert. NY, NY: Purdue Pharma;1996.
2. Drug Facts & Comparison, 2002.
3. Drug Information Handbook, 2001-2002.
4. Physicians' Desk Reference, 2002.
5. Opioids.Com. Narcotic Analgesics: Oxycontin. <http://opioids.com/oxycodone/prescribe.html>
6. Roth S, Fleischmann R, Burch F, et al. Around-the-clock, controlled-release oxycodone therapy for osteoarthritis-related pain: placebo-controlled trial and long-term evaluation. *Arch Intern Med* 2000;160(6):853-60.
7. Hart A and Hopkins C. ICD-9-CM Expert for physicians, volumes 1 and 2. 6th edition. 2002.

Client Approval

Please have an authorized representative execute this PA criteria verifying receipt by the client and that all elements contained herein are understood.

Client Name: _____

Signature: _____

Date: _____

